International Journal of Research in Medical Sciences
Thapa M et al. Int J Res Med Sci. 2022 May;10(5):1079-1087
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20221179

Original Research Article

Estimation of extra-pancreatic necrosis volume and its correlation with the clinical outcome in acute pancreatitis

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Received: 17 January 2022
Revised: 01 February 2022
Accepted: 31 March 2022

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ABSTRACT

Background: The aim of study was to measure extra-pancreatic necrosis volume in acute pancreatitis and associate with the clinical outcome and to determine the threshold volume of extra-pancreatic necrosis that predicts severity of acute pancreatitis.
Methods: Hospital based observational study was carried out in the department of radiodiagnosis, Armed forces medical college, Pune, Maharashtra. All cases referred for CT scan in suspected cases of acute pancreatitis (by clinical and/or biochemical parameters) as a part of institutional protocol were included in the study. Multiplanar reconstruction with volumetric analysis was done for measuring the extra-pancreatic necrosis volume (EPNV) using inherent CT scanner volume assessing software.
Results: Out of total 41 patients studied, more than one cause was identified in 9 patients. The most common cause of acute pancreatitis was alcohol use 32 (64%), followed by gallstone and diabetes mellitus (8% each). There was a positive correlation between EPNV and duration of hospitalization which was statistically significant with Spearman's correlation coefficient of 0.579 and $p<0.001$.
Conclusions: Our study showed highly significant correlation between the EPNV and the prediction of end organ failure, systemic infection, duration of hospital stay and need for intervention. Statistically patient presenting with EPNV of more than 100 ml was closely associated with end organ failure; hence EPNV may be used as a useful scoring system. This study has highlighted the convenient and easier technique of predicting clinical outcome in patient by simply assessing the severity of acute pancreatitis by measuring EPNV.

Keywords: Acute pancreatitis, Extra-pancreatic necrotic volume, Computed tomography, Computed tomography severity index, Organ failure

INTRODUCTION

Acute pancreatitis is a common gastroenterological emergency with significant morbidity and mortality depending on the severity.[1] Acute pancreatitis is generally classified into mild pancreatitis and severe pancreatitis.[2] Mild pancreatitis responds well to supportive care whereas severe acute pancreatitis requires monitoring and targeted therapies and has poorer prognosis.[3] Severe pancreatitis occurs in 20% to 30% of all patients with acute pancreatitis and is characterized by a protracted clinical course, multi organ failure and pancreatic necrosis.[4]

With the development of modern diagnostic modalities, several clinical, biochemical and radiological scoring systems have been developed to predict the adverse outcomes in acute pancreatitis.[5] It is imperative to detect

the early disease process, so that potential complications can be monitored more closely or empirically treated.[6]

The role of imaging is not only to diagnose acute pancreatitis but to demonstrate the presence and extent of pancreatic necrosis and the complications of acute pancreatitis. CT has precision of 87% sensitivity and specificity of 100% for revealing of extra pancreatic necrosis.[4,7]

Contrast enhanced CT (CECT) is considered to be gold standard imaging modality in the evaluation of patients with acute pancreatitis. Over the years, it has been established that CECT is able to depict and quantify pancreatic parenchymal injury except for very mild forms and detect pancreatic necrosis and local complications.[4]

CT severity index remains the most widely used radiologic scoring system and is a better prognostic indicator than numeric systems owing to its greater sensitivity and specificity. Modified CT severity index is one of the radiological parameters which is easier to calculate and correlates more closely than other radiological parameters and clinical outcomes; like the occurrence of infection, organ failure, the need for surgical or percutaneous intervention and death.[3,9,10]

Patients with necrotic pancreatitis have increased morbidity and intervention rates compared to patients with interstitial oedematous pancreatitis.[12] Recent studies showed significant association between volumetric measurement of extra-pancreatic necrosis and clinical outcome especially occurrence of infection and development of organ failure.[5]

The purpose of this study was to determine the extra pancreatic necrosis volume that objectively predicts severe acute pancreatitis and assess the reliability of this simple grading system in predicting severe acute pancreatitis as compared to current scoring system.[1]

METHODS

Hospital based observational study was carried out from October 2015 to October 2017 in the department of radiodiagnosis and imaging, Armed forces medical college, Pune, Maharashtra. The study was approved by institutional ethical committee. Informed consent was obtained from each patient as per WHO format. This prospective study included sample size of 41 individuals of either sex, age who were suspected cases of acute pancreatitis (by clinical and/or biochemical parameters), referred to CT scan were selected for the study. Pregnant women and patients lost to follow up/transferred to another hospital without early CT scan were excluded of the study. Sample size (n) was calculated based on following formula,

$$n = \frac{Z\text{^}2\ 1-\alpha \div 2\{\pi 1(1-\pi 1)+\pi 2(1-\pi 2)\}}{d^2},$$

H0: π1=π2,

H1: π1≠π2,

π1≥100 ml extra pancreatic necrosis volume- percentage prevalence of clinical outcome,

π2≤100 ml extra pancreatic necrosis volume- percentage prevalence of clinical outcome,

d: the absolute precision required on either side of the difference π1-π2.

To test whether there was significant difference in clinical outcomes in less than 100 ml and more than 100 ml extra pancreatic necrosis volume.[5]

In this study data and measurement was obtained using a CT machine (Siemens, Somatom Sensation 16, Erlanger, Germany). This volumetric data was used to reconstruct 5 mm contiguous sections which were loaded on to the volume software for liver volume calculation.

The various technical parameters used were,

Kilo voltage (kV)=120, tube current (mAs)=210, slice thickness=5.0 mm, collimation=16×0.75 mm, rotation time=0.37 sec to 0.50 sec, feed/rotation=12.0 mm, kernel=B 30f medium smooth, window=abdomen, contrast=iodinated non-ionic contrast (300 mg/ml), rate of infusion of iodinated intravenous contrast=2.5 to 3.0 ml/sec, scan delay=40 to 50 sec, direction-cranio-caudal, window level=40, window width=300, gantry rotation=zero degree.

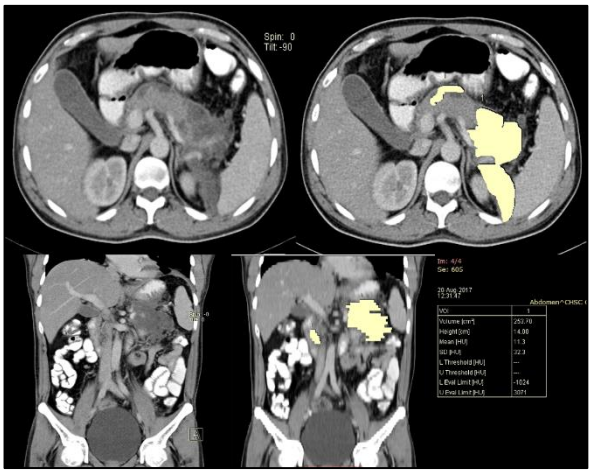

Figure 1: Measurement of extra-pancreatic necrotic fluid volume by free hand outlining (shown by arrow) in a 39 years old alcoholic patient with evidence of infection and organ failure, CT performed on 3rd day and estimated EPNV was 253.7 ml.

Early CT examination was performed (2-6 days from the onset of symptoms) using (16 detector row Siemens) CT

scanner. CECT examinations was performed with water soluble non-ionic iodinated contrast media administered intravenously with a dose of 300 mg I/kg body weight of the patient.

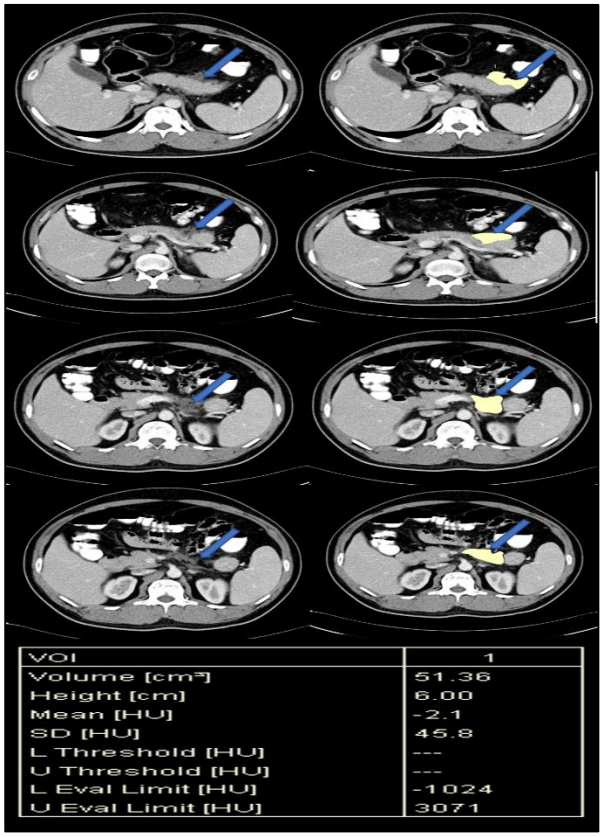

Figure 2: Free hand outlining (shown by arrow) the extra-pancreatic necrotic volume and the result of total volume measured.

Rate of contrast injection was 2.5 to 3.0 ml/sec through a pressure injector. All patients were scanned in portal-venous phase with post contrast initiation delay of 40 to 50 sec depending on the heart rate and age of the individual. Helical scan was obtained with reconstruction at 5 mm intervals with an appropriate kVp and mA in a single breath hold. Contrast was not administered to patients with renal dysfunction or known allergic reaction to contrast. In such cases non contrast study was performed.

Multiplanar reconstruction with volumetric analysis was done for measuring the extra-pancreatic necrosis volume using inherent CT scanner volume assessing software. Extra-pancreatic necrosis includes peripancreatic and contiguous retroperitoneal fat necrosis defined by fat infiltration, collection of fluid or collection of both fluid and solid components. Peritoneal fluids were not included in the study. Patient was followed up for at least 3 months and clinical outcomes tabulated. The various parameters estimated to determine clinical outcome included were: evidence of infection, surgical intervention performed, percutaneous intervention done, evidence of organ failure (modified Marshall scoring system for organ dysfunction was used), death.

Volume of the extra-pancreatic necrotic volume was measured using contrast enhanced CT axial images at 5 mm intervals by the help of software enabled free-hand outlining of the perimeter of the necrotic areas as defined in the study (Figure 1 and 2). All tracings were performed by a single investigator trained to recognize the relevant organ boundaries. Peritoneal fluids were excluded from the outline. After completion of the free-hand outlining of each and every section of the necrotic areas, automated volume was determined by software provided at the Workstation. Data collected was entered simultaneously into Microsoft excel worksheets designed appropriately (data sheet). The collected data was analysed using software Statistical package for social sciences (SPSS) Version 21. Spearman's rank correlation test, scatter plot and regression analysis were done on the compiled data.

RESULTS

A total of 41 patients who met the inclusion criteria were included in the study. There were 38 (92.7%) male and 3 (7.3%) female participants. The median age of the participants was 39 years with inter quartile range of 33-44.5 years.

Table 1: Causes of pancreatitis.

Etiology	Number	Percentage
Gall stone	4	8
Alcohol use	32	64
Ampullary tumor	2	4
After endoscopy	1	2
Both ATT and ART	2	4
ATT	2	4
DM	4	8
UGI bleeding	1	2
Unknown	2	4
Total response	50	100

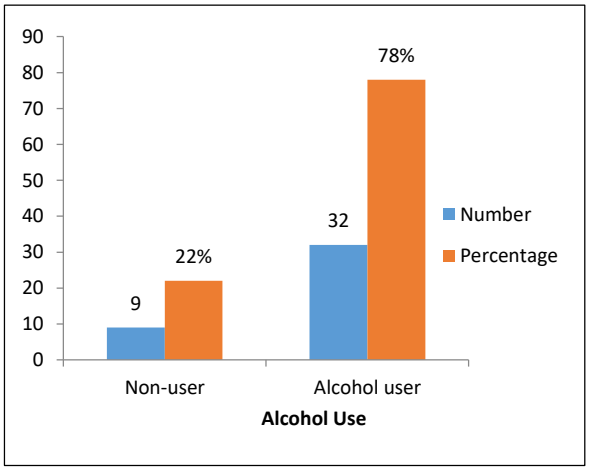

Figure 3: Distribution based on alcohol use.

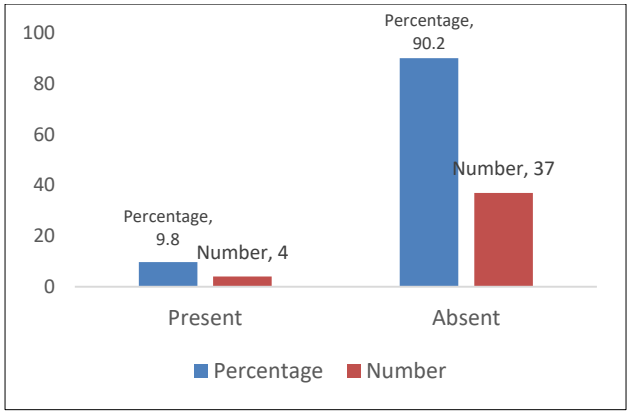

Figure 4: Distribution based on presence of gall stone.

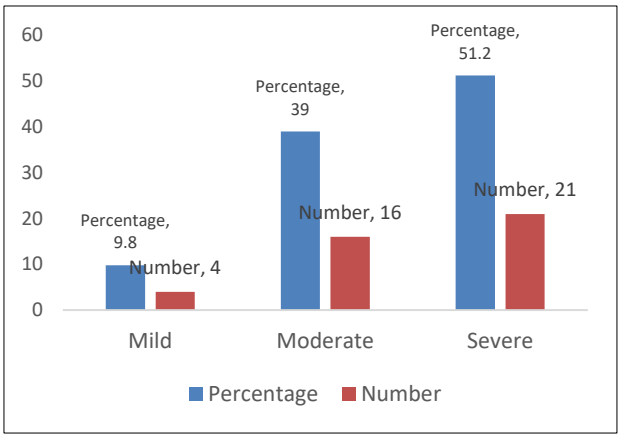

Figure 5: Patient distribution based on the CT severity index.

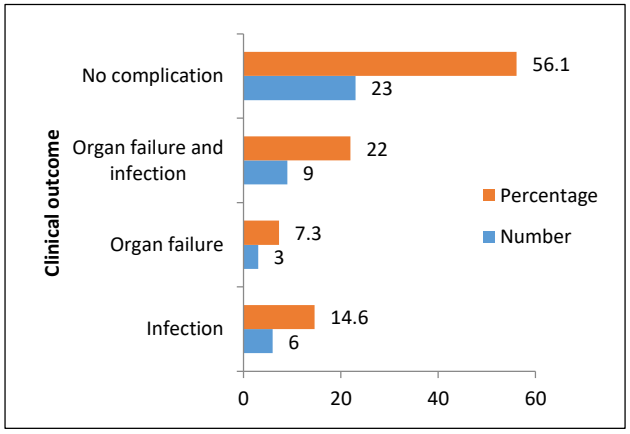

Figure 6: Distribution of patients according to the clinical outcomes.

Cause of pancreatitis

Out of total 41 patients studied, more than one cause was identified in 9 patients. The most common cause of acute pancreatitis was alcohol use in 32 (64%) patients (Figure 3). This was followed by gallstone and diabetes mellitus (8% patients each) (Figure 4). No cause could be identified in 2 patients (Table 1).

Of 41 patients studied, 18 patients developed one or more complications. Altogether, 9 patients developed both infection as well as organ failure while 3 patients developed organ failure and 6 patients developed infection. There were no deaths reported (Figure 6).

Table 2: Correlation between extra pancreatic necrosis volume and duration of hospitalization.

Correlation		Extra pancreatic necrosis volume	Duration of hospitalization
Extra pancreatic necrosis volume	Spearman's rho Correlation Coefficient	1.000	0.579
	Sig. (2-tailed)	.	<0.0001
	N	41	41
Duration of hospitalization	Spearman's rho Correlation Coefficient	0.579	1.000
	Sig. (2-tailed)	<0.001	.
	N	41	41

Extra pancreatic necrotic volume and duration of hospitalization

There was a positive correlation between extra pancreatic necrosis volume and duration of hospitalization which was statistically significant with Spearman's correlation coefficient of 0.579 and p<0.001 (Table 2).

Extra pancreatic necrotic volume and infection

Altogether, 15 of the patients went on to develop infection with the median extra pancreatic necrotic volume of 143 ml (inter quartile range 110 to 173). The remaining 26 patients did not develop infection and their median extra pancreatic necrotic volume was 54.5 ml (inter quartile range of 30-108). The difference was statistically significant with p<0.001 (Table 3).

Extra pancreatic necrotic volume and organ failure

Of the 41 patients studied, 12 patients developed organ failure. Those who developed organ failure had median extra pancreatic necrotic volume of 143 ml with inter quartile range 108.5 to 170.25. The remaining 29 of 41 participants did not develop organ failure and had the median extra pancreatic necrotic volume of 60 ml with inter quartile range of 30-1116.5 (Table 4).

There was statistically significant association between the development of organ failure and the extra pancreatic necrosis volume with p<0.001.

Table 3: Association of extra pancreatic necrosis volume with the development of infection.

Infection	N	Extra pancreatic necrosis volume			Mann Whitney U	P value
		Mean	Std. deviation	Median (IQR)		
Infection	15	144.8000	51.23224	143 (110,173)	54	<0.001
No infection	26	77.6154	72.67356	54.5(30, 108.0)		

Table 4: Association of extra pancreatic necrosis volume with the development of organ failure.

Organ failure	N	Extra pancreatic necrosis volume			Mann Whitney U	P value
		Mean	Std. deviation	Median (IQR)		
Yes	12	145.2500	51.34398	143(108.5, 170.25)	64	0.002
No	29	84.3793	73.50190	60 (30,1116.5)		

Table 5: Association of extra pancreatic necrosis volume with need for intervention.

Need for Intervention		N	Extrapancreatic Necrosis Volume			Mann Whitney U	P values
			Mean	Std. deviation	Mean (IQR)		
Percutaneous	Yes	4	138.0000	45.10728	120 (108.5, 185.5)	42	0.160
	No	37	98.3243	74.52295	98 (32.5,138.5)		
Surgical	Yes	2	120.0000	14.14214	120 (110, 130)	26.5	0.449
	No	39	101.2821	74.48983	100 (33, 143)		
Both	Yes	2	120.0000	14.14214	120 (110, 130)	26.5	0.449
	No	39	101.2821	74.48983	100 (33, 143)		

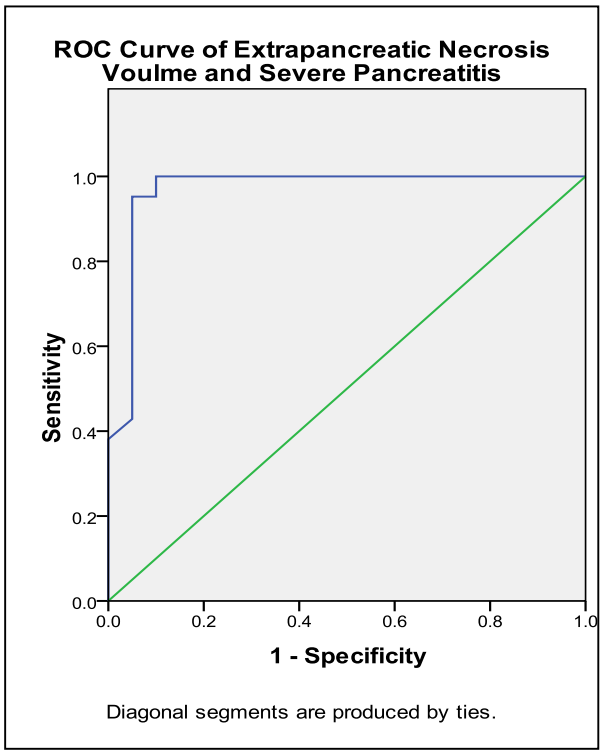

Figure 7: Receiver operating characteristics curve.

Need for intervention

Surgical intervention was required in 1 (2.44%) patients. 1 patient who underwent laparotomy and USG guided aspiration had infected pseudocyst.

In our study, the patients with mild pancreatitis according to MCTSI scoring underwent no surgical intervention. Two patients (4.88%) received surgical as well as percutaneous drainage for infected pancreatic pseudocyst.

Three of patients (7.32%) had large pancreatic pseudocyst, underwent percutaneous drainage. All 6 patients who had need for intervention had severe form of pancreatitis and there extra pancreatic necrosis volume was above 100 ml (Table 5).

The area under curve is 0.968 which is more than 0.5 and statistically significant with p<0.001 (Figure 7). Thus, the extra pancreatic necrosis volume can be used for screening of severe pancreatitis.

With the co-ordinates of the ROC curve, it was found that at volume 101 ml, the sum of sensitivity and specificity is the highest (highlighted in the table) and thus it was determined as the cut off value for diagnosing severe pancreatitis in this study; at which sensitivity is 95.2 and specificity is 95.0 (Table 6).

Relationship of modified CT severity index with extra pancreatic necrosis volume and duration of hospitalization

Table 7 outlines three different groups according to the modified CT severity index and the number of patients in each of the three groups along with their median extra pancreatic necrosis volume and the hospitalization duration.

Median test shows that there was statistically significant difference among the group medians with p<0.001 which means the median extra pancreatic necrosis volumes were significantly different among the three categories.

Table 6: Coordinates of the receiver operating characteristics curve.

Positive if greater than or equal to	Sensitivity	1 - specificity
17.0000	1.000	1.000
18.5000	1.000	0.950
21.0000	1.000	0.900
23.5000	1.000	0.850
26.0000	1.000	0.800
29.0000	1.000	0.750
31.0000	1.000	0.600
32.5000	1.000	0.550
33.5000	1.000	0.500
37.5000	1.000	0.450
47.0000	1.000	0.400
54.5000	1.000	0.300
58.0000	1.000	0.250
65.5000	1.000	0.200
80.5000	1.000	0.150
94.0000	1.000	0.100
99.0000	0.952	0.100
101.0000	0.952	0.050
105.0000	0.905	0.050
109.0000	0.810	0.050
111.5000	0.714	0.050
116.5000	0.667	0.050
125.0000	0.524	0.050

Similarly, the median duration of hospitalization was significantly different among the three different groups with p<0.001 (Table 8).

Table 9 outlines the number of observations in each of the three categories based on the modified CT Severity Index with and without infection. There was statistically significant association observed between the modified CT severity index category and the development of infection with p value of 0.0071.

Similarly, Table 10 outlines the number of observations in each of the three categories based on the modified CT severity index with and without organ failure. The Chi square test with Yates correction showed no statistically significant association between the modified CT severity index category and development of organ failure with p value of 0.056.

DISCUSSION

Clinical assessment of progression of disease and prediction of the severity in cases of acute pancreatitis has been inadequate unless aided with imaging modalities.

Prediction of severity is vital and plays an important role in management decision and in reducing the morbidity and mortality associated with severe acute pancreatitis.

The different severity scoring system studied in the past and proven to be indicators of the clinical severity are Ranson score, APACHE II, Glasgow score, Marshall and SOFA (sepsis-related organ failure assessment) scoring system.[5,16] But, none of the afore mentioned clinical scoring systems has proven to be the exact indicator of the adverse clinical outcome.

Table 7: Distribution of patients according to modified CT severity index, extra pancreatic necrosis volume and duration of hospitalization.

Modified CT severity index	Frequency	%	Extra pancreatic necrosis volume: median (IQR)	Duration of hospitalization
Mild	4	9.8	26 (23.25,31)	7 (7,13)
Moderate	16	39.0	47 (30,68.25)	10 (7,11.5)
Severe	21	51.2	130 (110,185.5)	16 (13.5,19)
Total	41	100.0	102 (33.5, 138.5)	12

Table 8: Association of modified CT severity index category with the duration of hospitalization.

Duration of hospitalization	Modified CT severity index			Median test p value
	Mild	Moderate	Severe	
>Median	1	2	17	<0.001
≤Median	3	14	4	

Relationship of modified CT Severity Index with clinical outcomes

Management of severe acute pancreatitis has changed from a more insistent surgical intervention towards the conservative approach, except when infected necrosis has been confirmed. Hence it was imperative from the treatment side to evaluate the severity of acute pancreatitis and the incidence of necrosis by CECT. Recent revision of Atlanta classification had established the presence of organ failure as main criteria for defining

severe acute pancreatitis; this study was hereby purposing a new and much simpler method of grading pancreatitis on the basis of extra-pancreatic necrosis volume. An estimated cutoff of 100 ml offers better sensitivity and specificity for predicting the incidence of organ failure or infection. It was seen to provide higher positive likelihood and diagnostic odds ratios and was effective and reliable technique for predicting the severity in cases of acute pancreatitis. Mean age of presentation was 40.7 years in our study. It was similar with study done by Thomas et al and Jauregui et al.[12,13] Chronic alcohol abuse and biliary stones were common in 4th and 5th decades and explained the high incidence of the acute pancreatitis in this age group. As alcohol was the most common etiological factor in our study and alcohol consumption was more common in males, a high M:F ratio was observed (12:1). Similar results were seen by Freeny et al.[15]

Table 9: Association of modified CT severity index with the development of infection.

Modified CT severity index	Infection		Total	Chi-square test p value with Yates correction
	No	Yes		
Mild	4	0	4	NA
Moderate	14	2	16	0.0071
Severe	8	13	21	
Total	26	15	41	

Table 10: Association of modified CT severity index with the development of organ failure.

Modified CT severity index	Organ failure		Total	Chi-square test p value with Yates correction
	No	Yes		
Mild	4	0	4	NA
Moderate	14	2	16	0.056
Severe	11	10	21	
Total	26	15	41	

NA: not applicable as one of the cell count is 0

Chronic alcohol abuse was the most common etiological factor in our study constituting 64% of cases. Similar results were observed by Dugernier et al and Freeny et al.[14,15] Studies done by Jauregui et al showed biliary stones as the predominant etiological agent.[13] Our study showed a significant correlation of grades of severity of pancreatitis based on both MCTSI and extra-pancreatic necrosis volume measurement with patient outcome parameters. Similar results were observed in the study done by Meyrignac et al.[5] In his study, conducted including 264 patients, significant relationships were found between extra-pancreatic necrosis volume and infection, hospital stay, need for intervention, organ failure and death ($p<0.001$ for all). The optimal threshold for predicting severe pancreatitis in this study was 100 ml.[5] In our study estimation of extra pancreatic necrotic volume was more closely associated with patient outcome than modified CTSI. This difference in statistical significance between MCTSI and in our study may be attributed to the inclusion of extra-pancreatic fluid volume that corroborates to the extra-pancreatic complications. Modified CTSI considered that the presence of ascites and pleural fluid may be responsible for the improved correlation with clinical outcome, because they may be early indicators of organ dysfunction. Important difference between the MCTSI and estimation of extra pancreatic necrosis volume is that, MCTSI differentiates only between presence and absence of acute fluid collections. Our study includes extra pancreatic necrosis as peripancreatic and contiguous retroperitoneal fat necrosis defined by fat infiltration, collection of fluid, or collection of both fluid and solid components. Unlike MCTSI peritoneal fluids were not included in our study.

Significant correlation between the severity of pancreatitis and the development of organ failure was seen only using the EPNV estimation ($p<0.001$).

In our study, EPNV to detect severe pancreatitis, sensitivity was 95.2% and specificity was 95% and positive predictive value of 95.2%. Hence at a cutoff 101 ml of extra pancreatic necrosis volume, it showed to be more useful technique for the screening in patients with severe acute pancreatitis than other CT techniques. Almost similar results were observed in study done by Meyrignac et al.[5]

The study done by Mole et al showed that extra-pancreatic complications are associated more closely with the multi organ failure than presence of infection.[17] In our study, patients who had extra-pancreatic complications had higher extra-pancreatic necrotic volume (>100 ml of EPNV). This resulted in the closer association with the severity of patient outcome. There was positive correlation between extra-pancreatic necrosis volume and duration of hospitalization. All patients who had evidence of infection had mean extra-pancreatic necrosis volume of more than 144 ml. Patients who developed organ failure during the period of acute pancreatitis had median extra pancreatic necrotic volume of more than 143 ml, whereas those who did not develop organ failure had median extra pancreatic necrotic volume of less than 60 ml. Interventional support as part of management was also indicated only in those patients having extra-pancreatic volume of more than 120 ml. This study has infact highlighted the convenient and easier technique of predicting clinical outcome in patient by simply assessing the severity of acute pancreatitis by measuring extra

pancreatic necrotic volume. Volume of more than 100 ml EPNV now indicates that it's a severe pancreatitis and should be managed accordingly.

In study done by Dugernier et al the role of pancreatic necrosis in prediction of patient clinical outcome was highlighted, where all patients with acute severe pancreatitis had evidence of necrosis on CT scan and similar findings were also seen in our study.[14]

There was no significant correlation between presence of necrosis and need of surgical intervention in our study. Similar results were seen in study done by Freeny et al.[15] This can be explained as patients presented with relapse and having pseudocyst and mild severity of pancreatitis but required surgical intervention. In our study no mortality was observed. The mean annual mortality rate for acute pancreatitis in the population was 1.3 per 100,000.[18]

Limitations

Our study had following important limitations: the sample size was inadequate to evaluate mortality and morbidity prediction based on CT criteria and EPNV, the study was done in a hospital which usually had cases of patients with similar etiology for acute pancreatitis mostly being chronic alcohol abuse; hence the other etiologies and their variety of clinical manifestation and outcomes could not be well represented, localization of fluid collections was often ambiguous and simple thickening of fascia due to small amount of fluid can be difficult to incorporate into the classification and if measured is often subjective, since the measurement of EPNV involved measuring slice by slice and various pockets in same slice, the free hand technique was often subject dependent and chances of over or underestimation of EPNV can occur, all patients with acute attacks of pancreatitis were included in study irrespective of whether first attack or relapse of pancreatitis. Hence, difference between first attacks and relapses could not be differentiated. The study seemed to have restricted grading system to the detection of severe acute pancreatitis and made less distinction between mild and moderate acute pancreatitis.

CONCLUSION

Maximum number of patients with acute pancreatitis was seen in the age group of 22-75 years of age with mean age of presentation being 40 years. Male to female ratio was 12:1 with male preponderance. Chronic alcohol abuse was the most common cause of pancreatitis (64%). The second commonest cause was gallstones (8%) and 4% of cases were idiopathic. Duration of hospital stay ranged from 6 to 31 days with mean duration of 9 days. Out of 41 patients 4 of the patients needed intervention for infected necrosis, 15 patients (36.5%) had evidence of infection, and 12 patients (29.26%) had evidence of organ failure. All these adverse clinical outcomes closely correlated to group of severe pancreatitis. On CECT abdomen these patients had extra pancreatic necrosis volume of more than 101ml. There was positive correlation between extra pancreatic necrosis volume and the clinical outcomes. All patients who had evidence of infection had mean EPNV of more than 144ml. Patients who developed organ failure had median EPNV of more than 143 ml and intervention was required for those patients who had EPVN of more than 120 ml.

Recommendations

There is significant correlation between the EPNV and the prediction of systemic infection, hospital stay, need for intervention and end organ failure. Statistically patient presenting with extra pancreatic necrosis volume of more than 100 ml was closely associated with end organ failure; hence EPNV may be used as a useful scoring system. A simple grading system based on an objective criterion such as a threshold of 100 ml of extra-pancreatic necrosis volume provides more reliable information for predicting acute pancreatitis clinical outcomes and proves to be the effective technique as compared to the various other existing scoring systems. EPNV is a very useful tool for the screening of patients with acute pancreatitis for the classification of severity accurately and to predict the clinical outcome. This will help the treating clinicians and will ultimately bring benefit to patients overall recovery.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Thapa M, Sharma P, Ram B. Estimation of extra-pancreatic necrosis volume and its correlation with the clinical outcome in acute pancreatitis. Int J Res Med Sci 2022;10:1079-87.